Attorney Docket No. 10123/00301 (03-008)

IN THE DRAWINGS:

Figure 2 and 7 have been amended. Two sheets of Replacement Drawings are enclosed along with two Annotated Sheets.

REMARKS

Claims 1, 7, 8, 18, 19 and 26 have been amended. Claims 6 and 27 have been cancelled. Claims 20-22 have been withdrawn. Figures 2 and 7 have been amended. No new matter has been added. Thus, claims 1-5, 8-19 and 23-26 are now remain pending in the present application. It is submitted that, in view of the following remarks, all of the presently pending claims are in condition for allowance.

The drawings stand objected to under 37 CFR 1.83(a). In support of the rejection, the Examiner stated that the features of claim 6 are not shown in the drawings. (*See* 11/21/07 Office Action, p. 2). Claim 6 is directed to a "second lumen [of the first housing] ... wherein a second flexible disk extends across the second lumen." Figure 2 of the drawings has been amended to indicate the positions of the lumens 22 and 24. In light of this amendment, it is respectfully submitted that the drawings comply with all requirements and withdrawal of this objection is requested.

Claim 19 stands rejected under35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In view of the amendments to claims 18 and 19, it is respectfully submitted that claim 19 is in condition for allowance.

Claims 1 - 5, 9 - 17 and 23 - 26 stand rejected under 35 U.S.C. § 102(b) as anticipated by Smith (U.S. Patent No. 4,244,379).

Amended claim 1 recites a *valve apparatus for dialysis applications*, comprising "a first flexible disk extending across a first lumen through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk, the first moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the first

flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk and, when a pressure at least as great as the threshold value is applied to the first flexible disk, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen" in combination with *a second flexible disk extending across a "second lumen, the second flexible disk including a plurality of second movable elements formed on opposite sides of at least one first slit extending through the second flexible disk, the second moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the second flexible disk, the second moveable elements are maintained in a closed position in which no flow is permitted past the second flexible disk and, when a pressure at least as great as the threshold value is applied to the second flexible disk, the second moveable elements are moved to an open position separated from one another along the at least one second slit permitting flow through the second lumen.*"

Smith fails to teach or suggest a "second lumen wherein a second flexible disk extends across the second lumen," as recited in claim 1. Specifically, Smith discloses only a check valve 110 with a cavity 114 fluidly connected to a proximal needle 122 and a distal needle 128. (*See* Smith, col. 5, ll. 6-57; Figs. 2-4). A valve member 130 with a slit 132 is disposed within the cavity 114 to allow for a flow of blood from the proximal needle 122 to the distal needle 128. (*Id.*). Smith does not disclose or suggest employing a "second lumen wherein a second flexible disk extends across the second lumen," as recited in claim 1. It is submitted that claim 1 is allowable over Smith for at least this reason.

Furthermore, Smith fails to teach or suggest a "*valve apparatus for dialysis applications*," as recited in claim 1. Rather, Smith is directed only to the withdrawal of blood from the body. (*Id.* at col. 4, ll. 7 - 13). It is well known in the art that dialysis procedures require that fluids be withdrawn from and infused into the body. It is submitted that the Smith device is inherently incapable of functioning in dialysis applications as it permits only the flow of fluids in one

direction, specifically in the direction from the proximal needle 122 to the distal needle 128 to remove a fluid from the body. (*Id.* at col. 5, ll. 34 - 57, Fig. 2). Furthermore, as noted above, Smith is directed only to the withdrawal of blood from the body and explicitly recites the undesirability of injecting any blood into the body. (*Id.* at col. 5, ll. 34 - 39). Smith therefore teaches away from a "valve apparatus for dialysis applications," as recited in claim 1.

It is therefore submitted that Smith fails to overcome the limitations of amended claim 1 and that claim 1 is allowable over Smith for at least this reason. Because claims 2 - 5 and 9 - 14 depend from, and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Similarly, claim 15 recites "[a] *dialysis connector* comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line; a valve element mounted within the flow passage of the housing, the valve element including a flexible disk extending across the flow passage, the flexible disk including a plurality of movable elements formed on opposite sides of a first slit extending through the flexible disk, the moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the flexible disk, the moveable elements are maintained in a closed position in which no flow is permitted past the flexible disk and, when a pressure at least as great as the threshold value is applied to the flexible disk, the moveable elements are moved to an open position separated from one another along the first slit permitting flow through the flow passage."

As noted above with regard to claim 1, Smith fails to teach or suggest a device capable of performing a dialysis and actually teaches away from such an application. Accordingly, it is submitted that Smith fails to teach or suggest a "dialysis connector", as recited in claim 15 and that claim 15 is therefore allowable over Smith for the same reason noted above with regard to

claim 1. Because claims 16 - 17 and 23 - 25 depend from, and therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claim 26 recites "[a] *flow shutoff device for dialysis applications*, comprising: a housing attachable to a patient line; and a pressure actuated valve mounted within the housing to selectively restrict flow therethrough, the valve comprising a flexible disk including a plurality of movable elements separated by a slit extending through the disk, the movable elements being biased toward a closed position and being movable to an open position when a pressure applied to the valve exceeds a predetermined threshold value, wherein flow through the housing is prevented when the movable elements are in the closed position."

As noted above with regard to claims 1 and 15, Smith fails to teach or suggest a "device for dialysis applications," as recited in claim 26. It is submitted that claim 26 is therefore allowable over Smith for the same reasons stated above in regard to claim 1.

Claims 1 - 4, 8, 12, 14 and 26 stand rejected under 35 U.S.C. § 102(b) as anticipated by Jones (U.S. Patent No. 2,720,881).

Amended claim 1 recites "valve apparatus for dialysis applications" comprising "a first flexible disk extending across a first lumen" and "a second lumen wherein a second flexible disk extends across the second lumen." Jones fails to teach or suggest "a second lumen wherein a second flexible disk extends across the second lumen," as recited in claim 1. Specifically, Jones only teaches a cap 14 with cuts 15 therein, the cap 14 being disposed in the tubular form 1. (*See* Jones, col. 1, li. 59 – col. 2, li. 8; Figs. 1, 2, 4). Jones makes no disclosure or suggestion of "a second lumen wherein a second flexible disk extends across the second lumen," as recited in claim 1.

Furthermore the Jones device is inherently incapable of being used in "dialysis

applications," as recited in claim 1. Specifically, the cap 14 is opened to flow via a pressure exerted thereupon by a medicament, the pressure being caused by the plunger 2. (*See* Jones, col. 2, ll. 58 - 71; Fig. 2). As stated above, dialysis applications require both infusion and withdrawal of fluid from the body and this would not have been possible for the Jones device as there would be no means of causing the cap to open for a withdrawal procedure. Specifically, it would not be possible to apply a plunger pressure from a side of the cap proximal to the body and therefore, a withdrawal cap according to Jones would not be functional. It is therefore respectfully submitted that claim 1 is allowable over Jones.

Because claims 2 - 4, 8, 12 and 14 depend from, and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 26 recites "[a] *flow shutoff device for dialysis applications*." As noted above with regard to claims 1 and 15, Jones is inherently incapable of being used in dialysis applications. Accordingly, it is submitted that Jones fails to teach or suggest "[a] *flow shutoff device for dialysis applications*," as recited in claim 26 and that claim 26 is therefore allowable over Jones.

Claims 1 - 7, 9 - 17 and 23 - 26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Martin (U.S. Patent No. 5,324,274) in view of Smith. In support of the rejection, the Examiner stated that it would have been obvious to have employed the pressure actuated valve assembly of Smith in the dual-lumen catheter of Martin. (*See* 11/21/07 Office Action, pp. 5 - 6).

It is submitted that the modification proposed by the Examiner would be detrimental to the Martin device as it would prevent the intake and return lumens of Martin from functioning properly. Specifically, the Martin device is directed to a dual-lumen catheter with a first lumen connected to one of the tubes 38 or 40 and opening at a distal end of the main body 22 at the openings 54 and a second lumen connected to the other one of the tubes 38 or 40 and opening at a distal end of the main body 22 at the openings 56. (*See* Martin, col. 2, li. 56 – col. 3, li. 2; Fig.

1). Martin further recites that one lumen "is normally the return lumen and the other lumen is the intake lumen and will originate at openings 54 providing entry to the catheter." (*Id.* at col. 2, ll. 62 - 65). Modifying the Martin device to include the valve member 130 of Smith would be detrimental thereto as the valve member 130 is a "one-way valve permitting blood flow [...] in one direction only, and to prevent inadvertent blood flow when the removal of blood is not desired." (*See* Smith, col. 5, ll. 34 - 38). Modifying the Martin device to include the valve member 130 of Smith would be detrimental as it would prevent the infusion of fluid into the body. Specifically, the backing disk 140 would prevent the infusion of fluid into the body. (*See* Smith, col. 5, ll. 48 - 53, Fig. 2). Accordingly, it is submitted that the proposed modification constitutes an improper hindsight reconstruction of the invention.

Furthermore, if the valve of Smith were to be modified with one valve placed in the Martin device in a normal configuration (i.e., allowing only withdrawal of blood) and a second valve placed in a reverse configuration (i.e., allowing only infusion of blood), the modification would still prove to be detrimental as there would be no means of actuating the reverse configuration valve. Specifically, Smith notes that the valve member 130 is actuated by the application of a suction or slight vacuum to an interior cavity to cause the valve member 130 to flex outward and force the slit 132 to open. (*See* Smith, col. 5, ll. 41 - 44). It is noted that there would be no available means to apply a suction to a distal end of the reverse configuration valve, wherein the distal end would be the direction approaching the body. Specifically, there would be no way to apply a suction or vacuum from inside the body and thus, no available means of opening the reverse configuration valve to flow. Accordingly, an infusion procedure would still not be possible with the valve of Smith.

It is therefore submitted that the modification proposed by the Examiner would be detrimental to the Martin device as it would prevent the intake lumen from functioning. It is therefore noted that the proposed modification is not allowable and that Martin and Smith, taken either alone or in combination, fail to teach or suggest "[a] *valve apparatus for dialysis*

applications, comprising a first flexible disk extending across a first lumen [...] *and further comprising a second lumen wherein a second flexible disk extends across the second lumen*," as recited in claim 1 and that claim 1 is therefore allowable.

Because claims 2 - 7 and 9 - 14 depend from, and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 15 recites "[a] dialysis connector." As noted above with regard to claim 1, the combination of Martin and Smith is not allowable. It is therefore submitted that Martin and Smith, either alone or in combination, fail to teach or suggest "[a] dialysis connector," as recited in claim 15 and that claim 15 is allowable.

Because claims 16 - 17 and 23 - 25 depend from, and therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Similarly, claim 26 recites "[a] flow shutoff device for dialysis applications." It is submitted that claim 26 is allowable over Martin and Smith, either alone or in combination, for the same reason noted above with regard to claims 1 and 15.

Claims 8 and 18 - 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Martin in view of Smith in further view of Jones.

Claim 8 depends from, and therefore includes all of the limitations of claim 1. As noted above, Martin and Smith fail to teach the limitations of claim 1. It is respectfully submitted that Jones fails to cure the deficiencies noted above in regard to claim 1. Accordingly, it is submitted that claim 1 is allowable over Martin, Smith and Jones, taken either alone or in combination and that claim 8 is allowable for the same reasons stated above in regard to claim 1.

Claims 18 and 19 depend from, and therefore includes all of the limitations of claim 15. As noted above, Martin and Smith fail to teach the limitations of claim 15. Jones fails to cure this deficiency. Accordingly, it is submitted that claim 15 is allowable over Martin, Smith and Jones, either alone or in combination. It is submitted that claims 18 and 19 are therefore allowable as dependent on an allowable base claim.

Claims 1 - 19 and 23 - 26 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4 - 12, 15 - 16 and 18 - 34 of U.S. Application Serial No. 10/608,660. In view of the terminal disclaimer submitted herewith, Applicants submits that this rejection has been obviated.

All issues raised by the Examiner having been addressed. Applicants therefore submit that the application is in condition for allowance.

Respectfully submitted,

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Appl. No. 10/630,885
Amdt. Dated Feb. 14, 2008
Reply to Office Action of Nov. 21, 2007
Annotated Sheet Showing Changes #1

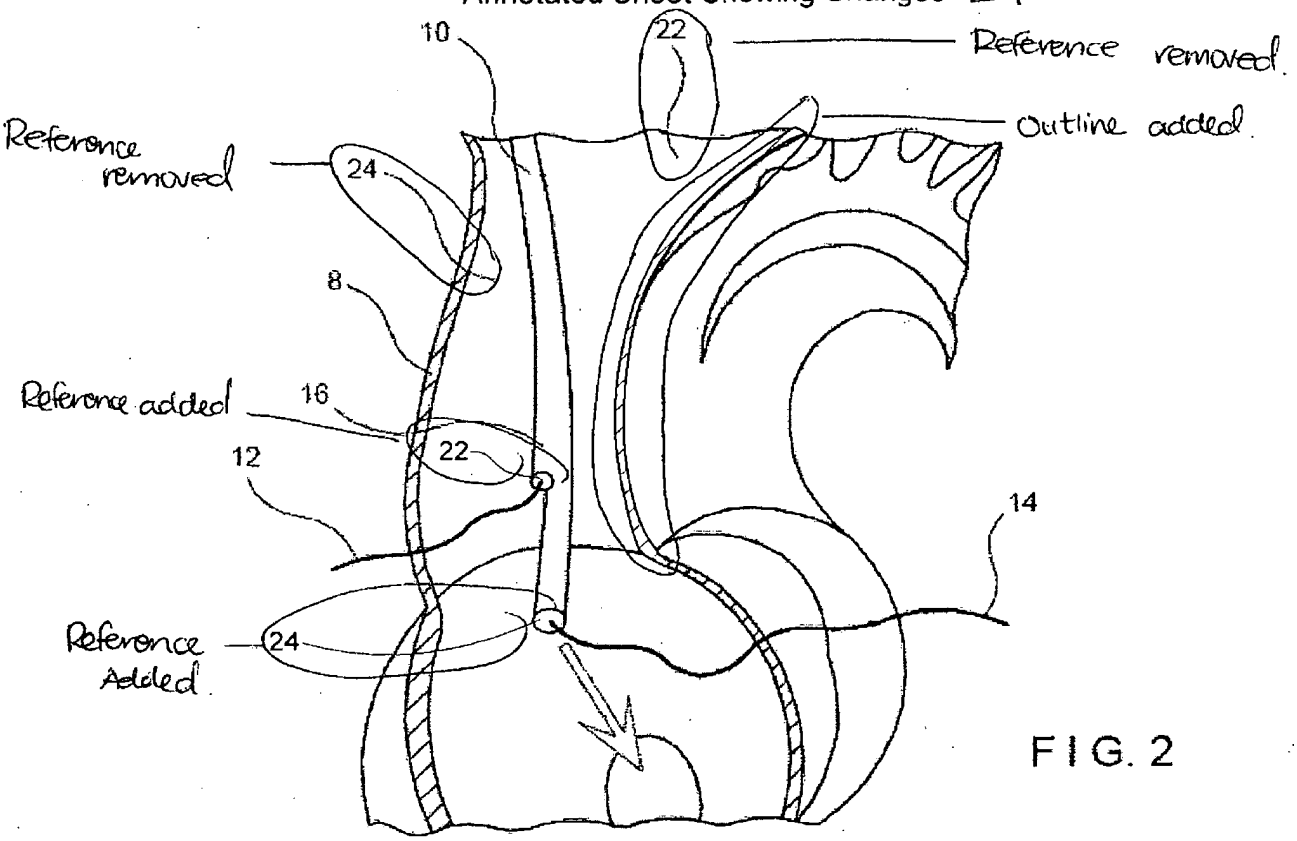

FIG. 2

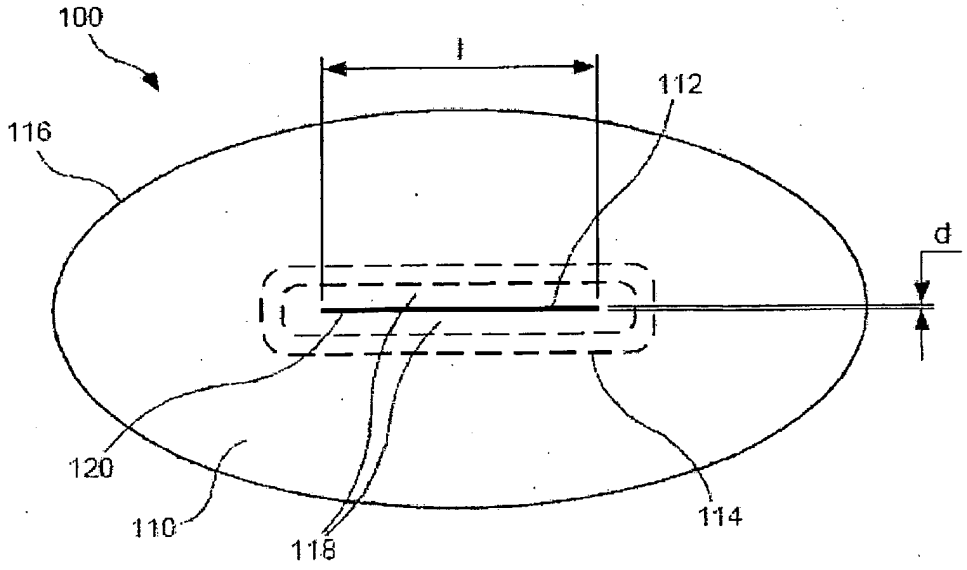

FIG. 3

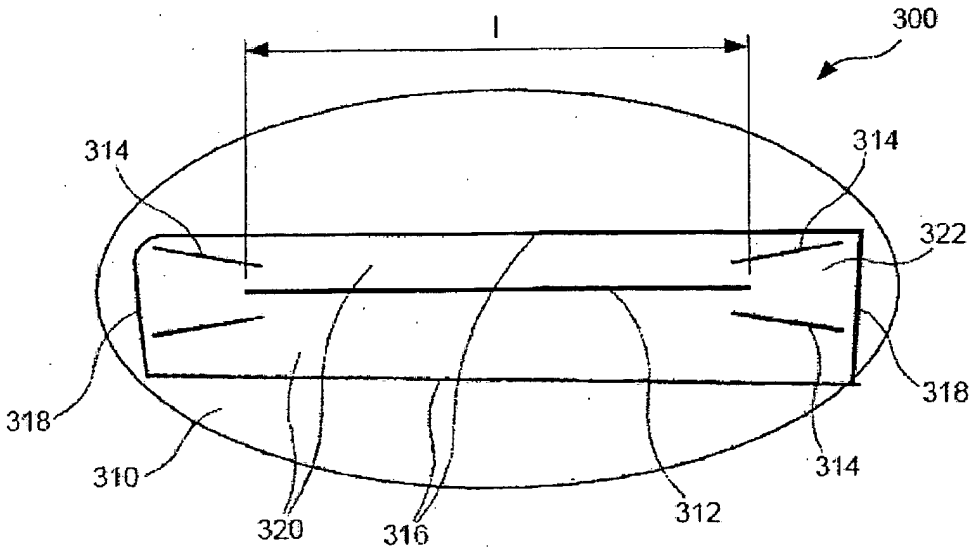
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FIG. 6

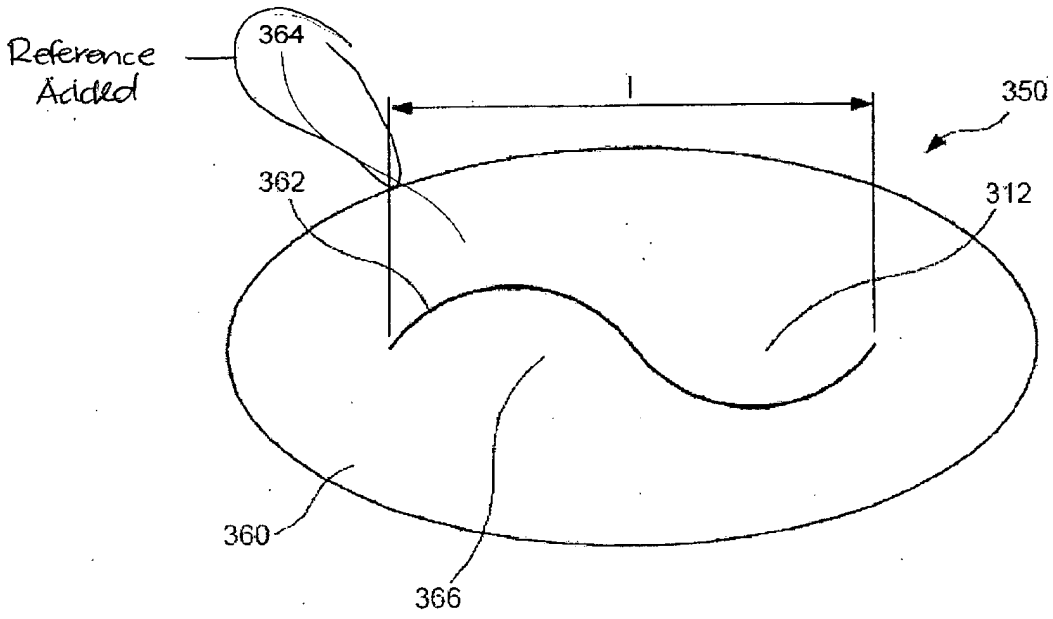
Reference Added
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FIG. 7